

**REMARKS****Amendment to the Specification**

Paragraph [0001] has been amended to consolidate the priority claims made at the time of filing, including priority claims (a) to the parent application, made in the preliminary amendment, and (b) to further applications, made in the declaration that accompanied the filing of the present application.

**Status of the Claims**

Claims 1-4, 6-9, 11-14, 17-26, 28-35, 38, 40-42 and 52-91 remain pending herein.

**Election between Groups I-V**

Election of one of groups I-V is required under 35 USC 121:

- I. Claims 1-4, 6-9, 11-14, 35, 52-63, 68, 69, 74, 75, 80, 81, 86, 87 drawn to microparticles with an adjuvant adsorbed to the surface, and compositions thereof.
- II. Claims 17-26, 28-34, drawn to methods of making microparticles with an adjuvant adsorbed thereto
- III. Claims 38, 64, 70, 76, 82, and 88, drawn to methods of delivering an adjuvant to a subject through administration of a microparticle with the adjuvant adsorbed to the surface
- IV. Claims 40, 65, 71, 77, 83 and 89, drawn to methods for the treatment of a disease through administration of a microparticle with the adjuvant adsorbed to the surface.
- V. Claims 41, 42, 66, 67, 72, 73, 78, 79, 84, 85, 90 and 91, drawn to methods of raising an immune response through administration of a microparticle with an adjuvant adsorbed to the surface.

Applicant hereby elects group I, for further prosecution on the merits. It is believed that claim 34 should also have also been included in this group (note that claim 35 is already included).

**Election requirements (A), (B), (C)(a), (C)(b), (C)(c) and (D)**

In addition to the election of one of groups I-V, the Office Action further requires election of the following:

(A) One of the types of polymers identified (e.g., in claim 3)

Applicant hereby elects a poly( $\alpha$ -hydroxy acid), with traverse, as discussed below.

(B) One of the embodiments where the surfactant is either anionic or cationic

Applicant hereby elects a cationic detergent, with traverse, as discussed below.

(C)(a) One of the embodiments where the antigen is either a polypeptide or a polynucleotide.

Applicant hereby elects a polynucleotide, with traverse, as discussed below.

(C)(b) One of the embodiments where the antigen is either a pathogenic organism or a tumor, and if a pathogen is elected to elect one of the pathogens listed (e.g., in claim 53)

Applicant hereby elects a pathogenic organism, specifically, meningitis B, with traverse, as discussed below.

(C)(c) One of the embodiments where the antigen is either adsorbed to the surface of the microparticle or encapsulated by the microparticle

Applicant hereby elects surface absorption, with traverse, as discussed below.

(D) One of the embodiments of adjuvants listed, e.g., in claim 12

Applicant hereby elects a CpG oligonucleotide, with traverse, as discussed below.

Applicant's reasons for traversal follow. The Office Action cites MPEP 806.04 and MPEP 808.01 as allegedly being in support of this requirement. These sections are reproduced below (underlined emphasis added):

#### **806.04 Independent Inventions**

If it can be shown that the two or more inventions are in fact independent, applicant should be required to restrict the claims presented to but one of such independent inventions. For example:

(A) Two different combinations, not disclosed as capable of use together, having different modes of operation, different functions or different effects are independent. An article of apparel such as a shoe, and a locomotive bearing would be an example. A process of painting a house and a process of boring a well would be a second example.

(B) Where the two inventions are process and apparatus, and the apparatus cannot be used to practice the process or any part thereof, they are independent. A specific process of molding is independent from a molding apparatus which cannot be used to practice the specific process.

(C) Where species under a genus are independent, for example, a genus of paper clips having species differing in the manner in which a section of the wire is formed in order to achieve a greater increase in its holding power.

Note that present situation is issue completely unlike MPEP 806.04(A), which involves two combination inventions, e.g., a shoe vs. a locomotive bearing, a painting process vs. a boring process, etc. MPEP 806.04(B) is also clearly inapplicable to the present situation.

MPEP 806.04(C) is directed to species. In this regard, and as noted in MPEP 808.01, the existence of independent inventions, *except in the case of species, is but rarely presented* (see below):

### **808.01 Independent Inventions**

Where the inventions claimed are independent, i.e., where they are not connected in design, operation, or effect under the disclosure of the particular application under consideration (MPEP § 806.04), *the facts relied on for this conclusion are in essence the reasons for insisting upon restriction*. This situation, except for species, is but rarely presented, since persons will seldom file an application containing disclosures of independent things.

Election requirements (A), (B), (C)(a), (C)(b), (C)(c) and (D), however, have not been presented as species elections. Hence, it is respectfully submitted that traversal is proper under the present circumstances.

### **Species Election**

As the Applicant has elected a poly(a-hydroxy acid) above, applicant is additionally required to elect one of the species listed, e.g., in claim 4. Applicant hereby elects poly(D,L-lactide-co-glycolide) as the species. Pending claims 1-4, 6-9, 11-14, 17-26, 28-35, 38, 40-42 and 52-91 read on this species.

### **Concluding Remarks**

As indicated in the Office Action, where Applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise

include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

As also indicated in the Office Action, some of the restriction requirements made above fall within the scope of PTO Linking claim practice. For example, claim 1 is considered a linking claim to the various microparticle compositions. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

Applicant submits that this application is in condition for allowance, early notification of which is earnestly solicited. The Examiner is encouraged to contact the undersigned at (703) 433-0510 to discuss any outstanding issues in this case.

#### **FEES**

The Office is authorized to charge any fees required in connection with this application, to deposit account number 50-1047.

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Respectfully submitted,



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I hereby certify that this document and any document  
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